

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF NORTH CAROLINA  
WESTERN DIVISION

GORDIAN MEDICAL, INC.,

Plaintiff,

vs.

LANIER M. CANSLER, Secretary of  
the North Carolina Department of Health  
and Human Services, in his official  
capacity; CRAIGAN L. GRAY,  
Director, Division of Medical  
Assistance, North Carolina Department  
of Health and Human Services, in his  
official capacity; and TARA R.  
LARSON, Chief Clinical Operations  
Officer, Division of Medical Assistance,  
North Carolina Department of Health  
and Human Services, in her official  
capacity,

Defendants.

Civil Action No. 5:10-CV-45

**VERIFIED COMPLAINT**

**INTRODUCTION**

Plaintiff Gordian Medical, Inc. ("Gordian Medical") is a Medicare Part B Durable Medical Equipment, Prosthetics, Orthotics and Supplies ("DMEPOS") supplier in good standing with the federal Medicare Program, furnishing wound care supplies (*i.e.*, surgical dressings and products to treat acute and chronic wounds) to Medicare beneficiaries through a delivery/shipping service across the country, including in North Carolina. Including the background of its predecessor in interest, Gordian Medical has more than 15 years' experience in wound care supplies and education. The largest supplier in the U.S. of wound care supplies to Medicare Part B beneficiaries, Gordian Medical maintains a nationwide staff of more than

150 nurses and physical therapists who have completed the required training and testing to be designated “Certified Wound Specialists” or similar certifications. Gordian Medical is licensed, bonded and accredited in all required subject areas, an approved provider under 34 states’ Medicaid programs and a network provider for more than 160 private insurance plans.

Under Medicare Part B, the federal Medicare program pays 80% of the Medicare fee schedule amount for wound care supplies Gordian Medical provides to Medicare beneficiaries; the individual beneficiaries are responsible for the remaining 20% of the allowable given amount, commonly referred to as the “coinsurance payment.”

Medicaid is a federal program established to provide medical benefits to certain categories of low-income persons. Medicaid is funded through both federal and state tax dollars and is administered by the States according to “state plans” prepared by the State and approved by the federal government. If a Medicare beneficiary is also eligible for Medicaid (commonly referred to as a “dual-eligible” beneficiary), federal law requires Medicaid to pay the 20% coinsurance payment to Gordian Medical and other DMEPOS suppliers for medical supplies provided under Medicare Part B, along with the annual deductibles owed under Medicare. Federal Anti-kickback laws bar the “routine” waiving of the coinsurance or annual deductible by Medicare suppliers.

The North Carolina Department of Health and Human Services, Division of Medical Assistance (the “Department”), which administers the Medicaid program in North Carolina, refuses to pay the 20% coinsurance and annual deductible payment as required by federal law for medical supplies provided by Gordian Medical under Medicare Part B to dual-eligible beneficiaries. As a result of this unlawful refusal to pay coinsurance, (1) indigent beneficiaries

may be denied medical care, (2) indigent beneficiaries may be asked to pay for medical care they can ill afford, and (3) Gordian is routinely denied payment to which it is lawfully entitled.

The Department appears to contend that the State is not obligated to pay the 20% coinsurance or annual deductible payment for dual-eligible beneficiaries because Gordian Medical is not enrolled in the North Carolina Medicaid Program as an approved provider. When Gordian Medical applied for enrollment in the North Carolina Medicaid Program on or about February 26, 2009, the Department denied Gordian Medical's application for enrollment on the ground that Gordian Medical, as an out-of-state provider, did not supply a "unique" product that was unavailable from in-state providers and was therefore not eligible for Medicaid enrollment. The Department's letter denying Gordian Medical's enrollment application stated that "[o]ut-of-state providers will be enrolled when the product they supply or manufacture is not available through an enrolled provider located within the state or border area."

Upon information and belief, the bases for the Department's positions are (1) that the Department may deny payment of the coinsurance payment for medical supplies provided by Gordian Medical to North Carolina dual-eligible beneficiaries because Gordian Medical is not enrolled in the North Carolina Medicaid Program and (2) that Gordian Medical is ineligible to be enrolled in the North Carolina Medicaid Program because it does not maintain a physical location in North Carolina or within 40 miles of the border of the State, even though Gordian Medical services such patients directly. These positions, and the North Carolina laws and regulations which purport to support these positions, are unenforceable as being preempted by federal law and/or as violating the Interstate Commerce Clause in Article I, Section 8 and the Equal Protection Clause of the Fourteenth Amendment to the United States Constitution.

Gordian seeks a declaratory judgment from this Court that federal law requires the North Carolina Medicaid program, which is administered by the Defendants in their official capacities, to pay to Gordian Medical the coinsurance payment for dual-eligible Medicare patients for medical supplies provided to said patients by Gordian Medical. In the alternative, Gordian Medical seeks a declaratory judgment from this Court that the Defendants may not deny Gordian Medical's application for enrollment as a provider in the North Carolina Medicaid Program on the basis of the physical location of Gordian Medical outside the state of North Carolina when serving dual-eligible beneficiaries.

### **DESCRIPTION OF THE PARTIES**

1. Plaintiff Gordian Medical, Inc. ("Gordian Medical") is a corporation organized and existing under the laws of the State of Nevada, with its principal place of business in Irvine, California.

2. Defendant Lanier M. Cansler ("Cansler") is the Secretary of the North Carolina Department of Health and Human Services and is a party here only in his official capacity.

3. Defendant Craigan L. Gray ("Gray") is the Director of the Division of Medical Assistance, North Carolina Department of Health and Human Services and is a party here only in his official capacity.

4. Defendant Tara R. Larson ("Larson") is the Chief Clinical Operations Officer of the Division of Medical Assistance, North Carolina Department of Health and Human Services and is a party here only in her official capacity.

### **JURISDICTION AND VENUE**

5. Jurisdiction is proper in federal court pursuant to 28 U.S.C. § 1331, as the first issue before the Court is whether the Defendants' denial of certain payments to Gordian

Medical is preempted by certain provisions of the federal Social Security Act and the regulations promulgated thereto.

6. This Court also has the power to declare that the Defendants' denial of said payments violates Article VI, § 2 of the United States Constitution by virtue of 28 U.S.C. § 2201, supported also by Gordian Medical's request to have this Court enjoin the Defendants from denying these payments to Gordian Medical.

7. Jurisdiction is also proper in federal court pursuant to 28 U.S.C. § 1331, as the second issue before the Court is whether the application of certain North Carolina laws and regulations violates the Interstate Commerce Clause in Article I, § 8 of the United States Constitution and the Equal Protection Clause to the Fourteenth Amendment to the United States Constitution.

8. Venue is proper in the United States District Court for the Eastern District of North Carolina pursuant to 28 U.S.C. § 113(a).

### **FACTUAL ALLEGATIONS**

9. Gordian Medical is a Medicare Part B Durable Medical Equipment, Prosthetics, Orthotics and Supplies ("DMEPOS") supplier in good standing, furnishing wound care supplies, *i.e.*, surgical dressings and products to treat acute and chronic wounds, to Medicare and Medicaid beneficiaries through a delivery/shipping service throughout the country.

10. Gordian Medical primarily furnishes wound care supplies to residents of long-term care facilities. Gordian Medical files claims with several Centers for Medicare and Medicaid Services ("CMS") authorized contractors for the processing and reimbursement of claims for supplies that are furnished to Medicare beneficiaries. Gordian Medical also furnishes wound care supplies to Medicaid beneficiaries.

11. Including the background of its predecessor in interest, Gordian Medical has more than 15 years' experience in wound care supplies and education.

12. Gordian Medical is the largest supplier in the United States of wound care supplied to Medicare Part B beneficiaries, and maintains a staff of more than 150 nurses and physical therapists who have completed the required training and testing to be designated "Certified Wound Specialists" or similar certifications.

13. Gordian Medical is licensed, bonded and accredited in all required subject areas, an approved provider under 34 States' Medicaid programs, and a network provider for more than 160 private insurance plans. Gordian Medical is also accredited by the Accreditation Commission for Health Care, Inc.

14. Gordian Medical has provided medical supplies to Medicare beneficiaries in North Carolina, including dual-eligible beneficiaries, since August 2008

15. Gordian Medical currently services a number of nursing homes and other long-term care facilities in North Carolina where a number of dual-eligible beneficiaries reside.

#### **Federal Medicare Benefits**

16. The Medicare Act was established under Title XVIII of the Social Security Act (the "Act"), 42 U.S.C. §§ 1395 – 1395ggg, and provides payment for the provision of covered medical care services, equipment, and supplies to eligible aged and disabled persons. Unlike Medicaid, discussed *infra*, Medicare provides health benefits to eligible individuals without regard to income or poverty status. Also unlike Medicaid, states do not contribute monies to pay claims submitted to Medicare. Instead, funds for the Medicare program come from payroll taxes on citizens, general revenues from the United States Treasury, and premiums paid by beneficiaries.

17. Medicare has four parts: Part A, which provides benefits for hospital, related post-hospital services, home health services, and hospice care benefits; Part B, which provides supplementary medical insurance for covered medical services furnished by providers, individual physicians and covered medical supplies, including DMEPOS; Part C, which expands the availability of managed care arrangements for Medicare patients; and Part D, which provides an outpatient prescription drug benefit. This dispute involves Medicare Part B.

### Federal Medicaid Benefits

18. Medicaid is a federal program established pursuant to Title XIX of the Act to provide medical benefits to certain categories of low-income individuals.

19. For each state or territory participating in the Medicaid program, both the federal government and the participating state or territory contribute monies. While the state or territory retains a considerable amount of discretion over the operation and administration of its Medicaid program, it must comply with strict regulatory guidelines established by the federal government.

20. For a state to receive federal monies under the Medicaid statute, the state must receive federal approval of a "State Plan" governing the operation of its Medicaid program by the Secretary of the United States Department of Health and Human Services. The State Plan generally explains the state's coverage rules and describes the methodology it will use to reimburse providers for the services and/or supplies they render to Medicaid recipients.

21. Specifically, the State Plan must be approved by the Centers for Medicare and Medicaid Services ("CMS"), part of the United States Department of Health and Human Services, the federal agency responsible for administering the Medicaid program. In order to earn such approval, State Plans must conform to conditions set forth in 42 U.S.C. § 1396a.



22. Only expenditures made under an approved State Plan are eligible for federal matching payments.

#### **North Carolina's Medicaid Program**

23. The State of North Carolina has a State Plan. A true and correct copy of North Carolina's current State Plan is available for review online at the North Carolina Department of Health and Human Services, Division of Medical Assistance's website: <http://www.dhhs.state.nc.us/dma/plan/sp.pdf>. The sections of the current North Carolina State Plan that are pertinent to this suit are attached hereto as Exhibit 1.

24. A state must comply with its State Plan.

25. North Carolina must comply with its State Plan.

26. The Defendants, acting in their official capacities through the Division of Medical Assistance, North Carolina Department of Health and Human Services, administer the Medicaid program in North Carolina.

#### **Medicare and Medicaid: Coinsurance and Annual Deductible Amounts**

27. Under Medicare Part B, the federal Medicare program pays 80% of the Medicare fee schedule allowable amount for a given item or service. The individual patient is responsible for the other 20%, commonly referred to as the coinsurance payment, and Medicare beneficiaries are also responsible for meeting an annual deductible before Medicare's obligation to make timely payment commences. See 42 U.S.C. § 1395s. In 2009, the annual deductible under Part B was \$135.

#### **"Dual-Eligible" Patients**

28. Some patients qualify for health care benefits under both the Medicare and Medicaid programs. These patients are commonly referred to as "dual-eligible" beneficiaries.



Dual-eligible beneficiaries qualify to receive Medicaid benefits because they are either categorically eligible or medically needy. The categorically eligible beneficiary population qualifies for Medicaid based upon an income and asset standard (which varies from state to state), while the medically needy meet a separate state income standard and are also aged, disabled, or a member of a family with dependent children. There are generally three distinct categories of dual-eligible beneficiaries: (a) Medicare beneficiaries who receive a full range of Medicaid benefits; (b) Qualified Medicare Beneficiaries (QMBs); and (c) Specified Low-Income Medicare Beneficiaries (SLMBs).

29. Unlike Medicare Part A, which has no annual or monthly premium for beneficiaries, there is a monthly premium, coinsurance and deductibles under Medicare Part B. Although a “dual-eligible” beneficiary may qualify for Medicare Part B, they are often incapable of paying the monthly premium to enroll in Medicare Part B, leaving the entire costs of paying for medical services and supplies directly on the State Medicaid Program.

30. Section 1843 of the Act addresses this financial problem by creating an option, known as the “buy-in program,” under which participating States with Medicaid plans may use State funds to pay for the monthly Part B premiums of dual eligible beneficiaries—hence, enrolling such beneficiaries directly in the Medicare Part B program. Once enrolled in the Medicare Part B program, the dual-eligible beneficiary receives medical items and services from Medicare participating providers and the Medicare Part B program becomes the payor for such items and services. This arrangement has the effect of transferring a significant portion of the medical costs for dual-eligible beneficiaries from the State and federally subsidized Medicaid program to the federally financed Medicare Part B program.

31. Importantly, while dual-eligible beneficiaries are eligible for Medicare Part A enrollment for hospital care and Part B insurance coverage for physician care, most cannot afford their coinsurance or annual deductible obligations, and federal law requires that the state's Medicaid program pay for such expenses on behalf of the dual-eligible Medicare beneficiary. 42 U.S.C. § 1395v.

32. Accordingly, Division of Medical Assistance, North Carolina Department of Health and Human Services must pay the 20% coinsurance and appropriate annual deductible for wound care supplies that Gordian Medical has provided to these dual-eligible beneficiaries and for which payment has been previously approved and made by the Medicare program.

33. From August 2008 to the present, the Defendants have unlawfully refused to pay Gordian Medical the Medicare annual deductible and coinsurance amounts owed for supplies that Gordian Medical has furnished to dual-eligible beneficiaries in North Carolina.

#### **Administering the Buy-In Program**

34. Section 3.2 of the North Carolina State Medicaid Plan is entitled "Coordination of Medicaid with Medicare Part B."

35. According to the North Carolina State Medicaid Plan and consistent with federal law, the North Carolina Medicaid Program pays the Medicare Part B premiums for Qualified Medicare Beneficiaries, Specified Low-Income Medicare Beneficiaries, Qualifying Individuals, and certain other Medicaid beneficiaries.

36. According to the North Carolina State Medicaid Plan and consistent with federal law, the North Carolina Medicaid Program "pays Medicare Part A and Part B annual deductible and coinsurance amounts for QMBs (subject to any nominal Medicaid copayment) for all services available under Medicare."

**The Defendants Have Denied Payments of the Medicare Part B Annual Deductible and Coinsurance Amounts for Dual-eligible Beneficiaries to Gordian Medical.**

37. Gordian Medical has submitted claims to the North Carolina Medicaid Program for payment of the 20% coinsurance and annual deductible payment for medical supplies provided by Gordian Medical to dual-eligible beneficiaries in North Carolina, for which Gordian Medical has already been paid the 80% of the allowable amount owed by the federal Medicare program.

38. Notwithstanding the requirements of federal law and the North Carolina State Medicaid Plan, the North Carolina Medicaid Program has refused to pay Gordian Medical any portion of the Medicare Part B coinsurance amount for medical supplies provided by Gordian Medical to dual-eligible beneficiaries in North Carolina.

39. The North Carolina Medicaid program has refused to pay Gordian Medical any portion of the Medicare Part B coinsurance amount for medical supplies provided by Gordian Medical to dual-eligible beneficiaries in North Carolina because Gordian Medical is not enrolled as a provider in the North Carolina Medicaid program.

40. The North Carolina Medicaid program has refused to pay Gordian Medical any portion of the Medicare Part B coinsurance amount for medical supplies provided by Gordian Medical to dual-eligible beneficiaries in North Carolina even though Gordian Medical is a Medicare Part B DMEPOS supplier in good standing with the Medicare Program and fully approved to provide wound care supplies via shipping/delivery services to dual-eligible beneficiaries.

41. Gordian Medical applied to enroll as a medical supply provider in the North Carolina Medicaid program. On or about March 12, 2009, Gordian Medical's application was

denied by the Department because “[t]he product/service your agency supplies is not a unique product.” In a letter from the Department to Gordian Medical, a copy of which is attached hereto as Exhibit 2, the Department explained that “[o]ut-of-state providers will be enrolled when the product they supply or manufacture is not available through an enrolled provider located within the state or the border area.”

42. The North Carolina Medicaid program has refused to enroll or pay Gordian Medical any portion of the Medicare Part B coinsurance amount for medical supplies provided by Gordian Medical to dual-eligible beneficiaries in North Carolina even though the determination that each individual Medicare Part B claim for a dual-eligible beneficiary submitted by Gordian Medical should be paid has already been made by the Medicare program.

43. Federal law does not allow the North Carolina State Medicaid program to deny payment of the 20% coinsurance and annual deductible payment for medical supplies provided to dual-eligible beneficiaries under Medicare Part B unless the payment that would be made by Medicare would exceed the payment amount that would be made by the North Carolina State Medicaid program.

44. North Carolina law does not allow the North Carolina State Medicaid program to deny payment of the 20% coinsurance and annual deductible payment for medical supplies provided to dual-eligible beneficiaries under Medicare Part B.

45. The terms of the North Carolina State Medicaid Plan, which are approved by the federal government, do not allow the North Carolina State Medicaid program to deny payment of the 20% coinsurance and annual deductible payment for medical supplies provided to dual-eligible beneficiaries under Medicare Part B.

46. North Carolina law states that payments under the North Carolina State Medicaid program “shall be made only . . . to pharmacies, physicians, dentists, optometrists, or other providers of health-related services authorized by the Department.” N.C. Gen. Stat. § 108A-55(b).

47. The Department has promulgated regulations with regard to “Out-of-State Services” which provide:

10A N.C.A.C. 22O.0119 – “Out of State Services”

(a) Reimbursement shall be made to providers outside of North Carolina in the case of an emergency, or if travel back to the state would endanger the health of the eligible recipient.

(b) Prior approval is required for non-emergency out-of-state services more than 40 miles outside North Carolina’s border.

48. Gordian Medical delivers medical supplies inside the State of North Carolina to dual-eligible beneficiaries under Medicare Part B. None of the dual-eligible beneficiaries under Medicare Part B in North Carolina are required to travel outside of the State to receive medical supplies from Gordian Medical.

49. The terms of the North Carolina State Medicaid Plan, which are approved by the federal government, do not require medical suppliers to be enrolled with the North Carolina Medicaid program in order for the North Carolina State Medicaid program to pay the 20% coinsurance and annual deductible payment for medical supplies provided to dual-eligible beneficiaries under Medicare Part B.

50. The terms of the North Carolina State Medicaid Plan, which are approved by the federal government, do not allow the Department to deny enrollment in the North Carolina Medicaid program for medical suppliers without a physical presence within the State of North Carolina or within the border area.

**The Social Security Act Preempts the North Carolina Medicaid Program from Making a Separate Payment Determination with Respect to the Coverage of Medical Supplies for Dual-Eligible Beneficiaries under Medicare Part B.**

51. Article VI of the United States Constitution provides, in pertinent part:

This Constitution, and the Laws of the United States which shall be made in Pursuance thereof, . . . shall be the Supreme law of the Land, and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary Notwithstanding.

52. The federal Medicare program has approved Gordian Medical as a DMEPOS supplier under Medicare Part B.

53. The federal Medicare program pays Gordian Medical 80% of the allowable amount for medical supplies provided by Gordian Medical to Medicare Part B beneficiaries, including dual-eligible beneficiaries.

54. The federal Medicare program has already paid 80% of the allowable cost for every claim that Gordian Medical submits to the North Carolina Medicaid Program for payment of the 20% coinsurance and annual deductible payment for medical supplies provided to dual-eligible beneficiaries and eligible QMBs under Medicare Part B.

55. Federal law requires the North Carolina Medicaid Program to pay the 20% coinsurance and annual deductible amounts for dual-eligible beneficiaries and eligible QMBs.

56. Absent an express provision of the North Carolina State Medicaid Plan, approved by the federal government, the North Carolina Medicaid program may not deny payment of the 20% coinsurance and annual deductible payment for medical supplies provided to dual-eligible beneficiaries under Medicare Part B.

57. There is no express provision in the North Carolina State Medicaid Plan, federal law or any other North Carolina law that allows the North Carolina Medicaid program to deny

payment of the 20% coinsurance and annual deductible payment for medical supplies provided to dual-eligible beneficiaries under Medicare Part B for any reason.

**Defendants' Denial of Gordian Medical's Application for Enrollment as a  
Provider in the North Carolina Medicaid Program Violates  
the Interstate Commerce Clause**

58. Article I, Section 8 of the United States Constitution provides, in pertinent part, that "[T]he Congress shall have the Power . . . To regulate Commerce . . . among the several States . . ."

59. Although Gordian is serving over 159 dual-eligible beneficiaries in the state of North Carolina, Defendants will not allow Gordian Medical to enroll as a Medicaid provider in the North Carolina Medicaid program because Gordian Medical does not maintain a physical location within the State of North Carolina or within the "border area," and lacking such a physical location, because the medical supplies provided by Gordian Medical are not "unique" in that such supplies are available "through an enrolled provider located within the state or border area."

60. Gordian Medical meets or exceeds all constitutionally-valid criteria to receive reimbursement from the North Carolina Medicaid program.

61. Despite an attempt to become an enrolled provider, the Defendants have denied Gordian Medical's application and payments for dual eligible patients because Gordian Medical does not maintain a physical location within the State of North Carolina or within the "border area," and lacking such a physical location, because the medical supplies provided by Gordian Medical are not "unique" in that such supplies are available "through an enrolled provider located within the state or border area."



62. There is no constitutionally permissible basis for Defendants' discriminatory treatment of Gordian Medical.

63. Defendants' discriminatory treatment of Gordian Medical with respect to payments for dual-eligible beneficiaries violates the Interstate Commerce Clause of the United States Constitution.

64. Defendants' discriminatory treatment of Gordian Medical with respect to the prohibition against enrollment as a provider in the North Carolina Medicaid program because Gordian Medical does not maintain a physical location within the State of North Carolina or within the "border area," and lacking such a physical location, because the medical supplies provided by Gordian Medical are not "unique" in that such supplies are available "through an enrolled provider located within the state or border area" violates the Interstate Commerce Clause of the United States Constitution.

65. Gordian Medical is and will continue to be damaged by Defendants' violations of the Interstate Commerce Clause of the United States Constitution.

**Defendants' Denial of Gordian Medical's Application for Enrollment as a Provider in the North Carolina Medicaid Program Violates the Equal Protection Clause of the Fourteenth Amendment to the United States Constitution**

66. The Fourteenth Amendment to the United States Constitution provides, in pertinent part, "[n]o State shall . . . deny to any person within its jurisdiction the equal protection of the laws."

67. Federal regulations make clear that a State Plan must provide for free choice of providers with limited exceptions, none of which are applicable to the present circumstances. 42 C.F.R. § 431.51 (2007).

68. Defendants are required to treat Gordian Medical as an in-state DMEPOS supplier and to reimburse Gordian Medical for the dual-eligible beneficiaries' coinsurance and annual deductible obligations to the same extent the Defendants make payments to in-state DMEPOS suppliers of wound care supplies.

69. Defendants are required to allow Gordian Medical to enroll as a provider in the North Carolina Medicaid program.

70. Defendants treat Gordian Medical differently from other medical supply providers that are located in the State of North Carolina or located within the "border area" solely because Gordian Medical furnishes medical supplies that are otherwise available from other DMEPOS suppliers located in the State of North Carolina or located within the "border area."

71. There is no constitutionally permissible basis for Defendants' discriminatory treatment of Gordian Medical.

72. Defendants' discriminatory treatment of Gordian Medical with respect to payments for dual-eligible beneficiaries violates the Equal Protection Clause of the Fourteenth Amendment to the United States Constitution.

73. Defendants' discriminatory treatment of Gordian Medical with respect to prohibition against enrollment as a provider in the North Carolina Medicaid program because Gordian Medical does not maintain a physical location within the State of North Carolina or within the "border area," and lacking such a physical location, because the medical supplies provided by Gordian Medical are not "unique" in that such supplies are available "through an enrolled provider located within the state or border area" violates the Equal Protection Clause of the Fourteenth Amendment to the United States Constitution.

74. Gordian Medical is and will continue to be damaged by Defendants' violations of the Equal Protection Clause of the Fourteenth Amendment to the United States Constitution.

### **GORDIAN'S CLAIMS**

75. Since August 2008, the North Carolina Medicaid Program has failed to make the 20% coinsurance and annual deductible payments for the wound care supplies furnished by Gordian Medical to North Carolina dual-eligible beneficiaries.

76. The Defendants' failure to pay said coinsurance violates federal law, and thus Gordian Medical seeks declaratory relief against the Defendants pursuant to 42 U.S.C. § 1983.

77. Specifically, Gordian Medical seeks a declaration that federal law requires the North Carolina Medicaid program, including agents and the third-party insurers through which they operate, to pay Gordian Medical the Medicare annual deductible and coinsurance amounts for wound care supplies provided to North Carolina dual-eligible beneficiaries.

78. To the extent this Court finds that the Defendants are permitted to deny payment of the Medicaid annual deductible and coinsurance amounts for wound care supplies provided to North Carolina dual-eligible beneficiary to Gordian Medical because Gordian Medical is not an enrolled provider with the North Carolina Medicaid program, Gordian Medical seeks a declaration that the Defendants may not deny Gordian Medical's application for enrollment on the basis of Gordian Medical's physical location or the type of medical supplies Gordian Medical provides to North Carolina dual-eligible beneficiaries.

### **FIRST CLAIM FOR RELIEF** **(Declaratory Judgment and Permanent Injunction)**

79. Paragraphs 1 through 78 of the Verified Complaint are realleged and incorporated herein by reference.

80. Federal law preempts state laws and actions by state officials that conflict with federal law.

81. For every claim submitted by Gordian Medical to the North Carolina Medicaid program for payment of the 20% coinsurance and annual deductible payment for medical supplies provided to dual-eligible beneficiaries under Medicare Part B, the federal Medicare program has already found the claim to be eligible for reimbursement and has, in fact, made a reimbursement to Gordian Medical for 80% of the Medicare-established fee schedule amount.

82. The Defendants' denial of Gordian Medical's claims for the 20% coinsurance and annual deductible payment for medical supplies provided to dual-eligible beneficiaries under Medicare Part B is preempted by the reimbursement determinations made by the federal Medicare program.

83. Pursuant to Article VI of the United States Constitution and Sections 1843 and 1902 of the Act (42 U.S.C. §§ 1395v, 1396a), Gordian Medical requests that this Court render a declaratory judgment that the Defendants' denial of Gordian Medical's claims for the 20% coinsurance and annual deductible payment for medical supplies provided to dual-eligible beneficiaries under Medicare Part B is preempted by federal law because the Defendants' denial of said claims conflicts with the reimbursement determination made by the federal Medicare program.

84. Pursuant to Article VI of the United States Constitution and Sections 1843 and 1902 of the Act (42 U.S.C. §§ 1395v, 1396a), Gordian Medical requests that this Court permanently enjoin the Defendants from denying claims submitted by Gordian Medical for the 20% coinsurance and annual deductible payment for medical supplies provided to dual-eligible beneficiaries under Medicare Part B.

**SECOND CLAIM FOR RELIEF**  
**(Declaratory Judgment and Permanent Injunction)**

85. Paragraphs 1 through 84 of the Verified Complaint are realleged and incorporated herein by reference.

86. Federal law preempts state laws and actions by state officials that conflict with federal law.

87. The federal Medicare program has approved Gordian Medical as a DMEPOS supplier for, *inter alia*, wound care supplies to Medicare beneficiaries throughout the country, including North Carolina. In North Carolina, Gordian Medical has six employees licensed as nurses or physical therapists and designated as Certified Wound Specialists. These clinical personnel assist nursing homes in assessing beneficiaries' needs for wound care supplies, and they provide education, as required by Medicare Supplier Standards and Quality Standards, to nursing home staff in the use and administration of such supplies. Gordian Medical ships wound care supplies directly to Medicare beneficiaries via a shipping/delivery service which is permitted by Medicare.

88. Defendants have denied payment of claims submitted by Gordian Medical for the 20% coinsurance and annual deductible payment for medical supplies provided to dual-eligible beneficiaries under Medicare Part B, upon information and belief, on the ground that Gordian Medical is not enrolled as a provider in the North Carolina Medicaid Program.

89. To the extent that Gordian Medical provides medical supplies to Medicare beneficiaries who are also dual-eligible beneficiaries and for whom the North Carolina Medicaid program is responsible to make the cost-sharing payments required by the Act, the Defendants' denial of payment to Gordian Medical because Gordian Medical is not an enrolled

provider in the North Carolina Medicaid Program is preempted by the provider's eligibility determination made by the federal Medicare program acting through their contractors and agents.

90. Pursuant to Article VI of the United States Constitution and Sections 1843 and 1902 of the Act (42 U.S.C. §§ 1395v, 1396a), Gordian Medical requests that this Court render a declaratory judgment the Defendants' denial of payment to Gordian Medical because Gordian Medical is not an enrolled provider in the North Carolina Medicaid Program conflicts with the provider eligibility determination made by the federal Medicare program.

91. Pursuant to Article VI of the United States Constitution and Sections 1843 and 1902 of the Act (42 U.S.C. §§ 1395v, 1396a), Gordian Medical requests that this Court permanently enjoin the Defendants from denying claims submitted by Gordian Medical for the 20% coinsurance and annual deductible payment for medical supplies provided to dual-eligible beneficiaries under Medicare Part B.

**THIRD CLAIM FOR RELIEF**  
**(Declaratory Judgment and Permanent Injunction)**

92. Paragraphs 1 through 91 of the Verified Complaint are realleged and incorporated herein by reference.

93. Defendants' actions and failure and refusal to allow Gordian Medical to enroll as a provider in the North Carolina Medicaid program because Gordian Medical does not maintain a physical location within the State of North Carolina or within the "border area," and lacking such a physical location, because the medical supplies provided by Gordian Medical are not "unique" in that such supplies are available "through an enrolled provider

located within the state or border area” unlawfully discriminates against Gordian Medical in violation of the Interstate Commerce Clause of the United States Constitution.

94. Defendants’ application of 10A N.C.A.C. 22O.0119 to Gordian Medical as a provider of medical supplies to dual-eligible beneficiaries under Medicare Part B unlawfully discriminates against Gordian Medical in violation of the Interstate Commerce Clause of the United States Constitution.

95. Pursuant to Article I, Section 8 of the United States Constitution, Gordian Medical requests that this Court render a declaratory judgment the Defendants’ denial of Gordian Medical’s application for enrollment as a provider in the North Carolina Medicaid program because Gordian Medical does not maintain a physical location within the State of North Carolina or within the “border area,” and lacking such a physical location, because the medical supplies provided by Gordian Medical are not “unique” in that such supplies are available “through an enrolled provider located within the state or border area” violates the Interstate Commerce Clause of the United States Constitution.

96. Pursuant to Article I, Section 8 of the United States Constitution, Gordian Medical requests that this Court render a declaratory judgment the Defendants’ application of 10A N.C.A.C. 22O.0119 to Gordian Medical violates the Interstate Commerce Clause of the United States Constitution.

97. Pursuant to Article I, Section 8 of the United States Constitution, Gordian Medical requests that this Court permanently enjoin the Defendants from excluding Gordian Medical as a provider in the North Carolina Medicaid Program because Gordian Medical does not maintain a physical location within the State of North Carolina or within the “border area,” and lacking such a physical location, because the medical supplies provided by Gordian



Medical are not “unique” in that such supplies are available “through an enrolled provider located within the state or border area.”

98. Pursuant to Article I, Section 8 of the United States Constitution, Gordian Medical requests that this Court permanently enjoin the Defendants from enforcing the provisions of 10A N.C.A.C. 22O.0119 against Gordian Medical.

99. Pursuant to Article I, Section 8 of the United States Constitution, Gordian Medical requests that this Court Gordian Medical requests that this Court permanently enjoin the Defendants from denying claims submitted by Gordian Medical for the 20% coinsurance and annual deductible payment for medical supplies provided to dual-eligible beneficiaries under Medicare Part B because Gordian Medical does not maintain a physical location within the State of North Carolina or within the “border area,” and lacking such a physical location, because the medical supplies provided by Gordian Medical are not “unique” in that such supplies are available “through an enrolled provider located within the state or border area.”

100. Pursuant to Article I, Section 8 of the United States Constitution, Gordian Medical requests that this Court Gordian Medical requests that this Court permanently enjoin the Defendants from denying claims submitted by Gordian Medical for the 20% coinsurance and annual deductible payment for medical supplies provided to dual-eligible beneficiaries under Medicare Part B on the basis of 10A N.C.A.C. 22O.0119.

**FOURTH CLAIM FOR RELIEF**  
**(Declaratory Judgment and Permanent Injunction)**

101. Paragraphs 1 through 100 of the Verified Complaint are realleged and incorporated herein by reference.

102. Defendants' actions and failure and refusal to allow Gordian Medical to enroll as a provider in the North Carolina Medicaid program because Gordian Medical does not maintain a physical location within the State of North Carolina or within the "border area," and lacking such a physical location, because the medical supplies provided by Gordian Medical are not "unique" in that such supplies are available "through an enrolled provider located within the state or border area" unlawfully discriminates against Gordian Medical in violation of the Equal Protection Clause of the Fourteenth Amendment to the United States Constitution.

103. Defendants' enforcement of 10A N.C.A.C. 22O.0119 as to Gordian Medical unlawfully discriminates against Gordian medical in violation of the Equal Protection Clause of the Fourteenth Amendment to the United States Constitution.

104. Defendants' denial of the payment of claims submitted by Gordian Medical for the 20% coinsurance and annual deductible payment for medical supplies provided to dual-eligible beneficiaries under Medicare Part B, while at the same time paying claims for similar medical supplies provided to dual-eligible beneficiaries under Medicare Part B submitted by DMEPOS providers with a physical location within the State of North Carolina or within the "border area", unlawfully discriminates against Gordian Medical in violation of the Equal Protection Clause of the Fourteenth Amendment to the United States Constitution.

105. Defendants' denial of the payment of claims submitted by Gordian Medical for the 20% coinsurance and annual deductible payment for medical supplies provided to dual-eligible beneficiaries under Medicare Part B, while at the same time paying claims for similar medical supplies provided to dual-eligible beneficiaries under Medicare Part B submitted by DMEPOS providers with a physical location within the State of North Carolina or within the

“border area” on the basis of 10A N.C.A.C. 22O.0119 unlawfully discriminates against Gordian Medical in violation of the Equal Protection Clause of the Fourteenth Amendment to the United States Constitution.

106. Pursuant to Section 1 of the Fourteenth Amendment to the United States Constitution, Gordian Medical requests that this Court render a declaratory judgment that the Defendants’ denial of Gordian Medical’s application for enrollment as a provider in the North Carolina Medicaid Program because Gordian Medical does not maintain a physical location within the State of North Carolina or within the “border area,” and lacking such a physical location, because the medical supplies provided by Gordian Medical are not “unique” in that such supplies are available “through an enrolled provider located within the state or border area” violates the Equal Protection Clause of the Fourteenth Amendment to the United States Constitution.

107. Pursuant to Section 1 of the Fourteenth Amendment to the United States Constitution, Gordian Medical requests that this Court render a declaratory judgment that the Defendants’ enforcement of 10A N.C.A.C. 22O.0119 as to Gordian Medical violates the Equal Protection Clause of the Fourteenth Amendment to the United States Constitution.

108. Pursuant to Section 1 of the Fourteenth Amendment to the United States Constitution, Gordian Medical requests that this Court render a declaratory judgment that the Defendants’ denial of the payment of claims submitted by Gordian Medical for the 20% coinsurance and annual deductible payment for medical supplies provided to dual-eligible beneficiaries under Medicare Part B, while at the same time paying claims for similar medical supplies provided to dual-eligible beneficiaries under Medicare Part B submitted by DMEPOS providers with a physical location within the State of North Carolina or within the “border

area”, violates the Equal Protection Clause of the Fourteenth Amendment to the United States Constitution.

109. Pursuant to Section 1 of the Fourteenth Amendment to the United States Constitution, Gordian Medical requests that this Court render a declaratory judgment that the Defendants’ denial of the payment of claims submitted by Gordian Medical for the 20% coinsurance and annual deductible payment for medical supplies provided to dual-eligible beneficiaries under Medicare Part B, while at the same time paying claims for similar medical supplies provided to dual-eligible beneficiaries under Medicare Part B submitted by DMEPOS providers with a physical location within the State of North Carolina or within the “border area” on the basis of 10A N.C.A.C. 22O.0119 violates the Equal Protection Clause of the Fourteenth Amendment to the United States Constitution.

110. Pursuant to Section 1 of the Fourteenth Amendment to the United States Constitution, Gordian Medical requests that this Court permanently enjoin the Defendants from excluding Gordian Medical as a provider in the North Carolina Medicaid Program because Gordian Medical does not maintain a physical location within the State of North Carolina or within the “border area,” and lacking such a physical location, because the medical supplies provided by Gordian Medical are not “unique” in that such supplies are available “through an enrolled provider located within the state or border area.”

111. Pursuant to Section 1 of the Fourteenth Amendment to the United States Constitution, Gordian Medical requests that this Court permanently enjoin the Defendants from enforcing the provisions of 10A N.C.A.C. 22O.0119 as to Gordian Medical.

112. Pursuant to Section 1 of the Fourteenth Amendment to the United States Constitution, Gordian Medical requests that this Court permanently enjoin the Defendants from

denying claims submitted by Gordian Medical for the 20% coinsurance and annual deductible payment for medical supplies provided to dual-eligible beneficiaries under Medicare Part B because Gordian Medical does not maintain a physical location within the State of North Carolina or within the “border area,” and lacking such a physical location, because the medical supplies provided by Gordian Medical are not “unique” in that such supplies are available “through an enrolled provider located within the state or border area.”

113. Pursuant to Section 1 of the Fourteenth Amendment to the United States Constitution, Gordian Medical requests that this Court permanently enjoin the Defendants from denying claims submitted by Gordian Medical for the 20% coinsurance and annual deductible payment for medical supplies provided to dual-eligible beneficiaries under Medicare Part B on the basis of the provisions of 10A N.C.A.C. 22O.0119.

#### **PRAYER FOR RELIEF**

Plaintiff Gordian Medical, Inc. respectfully prays the Court that it:

1. Issue a judgment declaring that the Defendants’ denial of Gordian Medical’s claims for the 20% coinsurance and annual deductible payment for medical supplies provided to dual-eligible beneficiaries under Medicare Part B is preempted by federal law and that the Defendants are permanently enjoined from denying such claims for payment submitted by Gordian Medical.

2. Issue a judgment declaring that the Defendants’ denial of Gordian Medical’s claims for the 20% coinsurance and annual deductible payment for medical supplies provided to dual-eligible beneficiaries under Medicare Part B on the ground that Gordian Medical is not enrolled as a provider in the North Carolina Medicaid program is preempted by federal law

and that the Defendants are permanently enjoined from denying such claims for payment submitted by Gordian Medical.

3. Issue a judgment declaring that the Defendants' denial of Gordian Medical's application for enrollment as a provider in the North Carolina Medicaid Program because Gordian Medical does not maintain a physical location within the State of North Carolina or within the "border area," and lacking such a physical location, because the medical supplies provided by Gordian Medical are not "unique" in that such supplies are available "through an enrolled provider located within the state or border area" violates the Interstate Commerce Clause of the United States Constitution and that the Defendants are permanently enjoined from excluding Gordian Medical as a provider in the North Carolina Medicaid Program because Gordian Medical does not maintain a physical location within the State of North Carolina or within the "border area," and lacking such a physical location, because the medical supplies provided by Gordian Medical are not "unique" in that such supplies are available "through an enrolled provider located within the state or border area."

4. Issue a judgment declaring that the Defendants' enforcement of the provisions of 10A N.C.A.C. 22O.0119 violates the Interstate Commerce Clause of the United States Constitution and that the Defendants are permanently enjoined from enforcing the provisions of 10A N.C.A.C. 22O.0119 as to Gordian Medical.

5. Issue a judgment declaring that the Defendants' denial of Gordian Medical's application for enrollment as a provider in the North Carolina Medicaid Program because Gordian Medical does not maintain a physical location within the State of North Carolina or within the "border area," and lacking such a physical location, because the medical supplies provided by Gordian Medical are not "unique" in that such supplies are available "through an

enrolled provider located within the state or border area” violates the Interstate Commerce Clause of the United States Constitution and that the Defendants are permanently enjoined from denying claims submitted by Gordian Medical for the 20% coinsurance and annual deductible payment for medical supplies provided to dual-eligible beneficiaries under Medicare Part B because Gordian Medical does not maintain a physical location within the State of North Carolina or within the “border area,” and lacking such a physical location, because the medical supplies provided by Gordian Medical are not “unique” in that such supplies are available “through an enrolled provider located within the state or border area.”

6. Issue a judgment declaring that the Defendants’ enforcement of the provisions of 10A N.C.A.C. 22O.0119 as to Gordian Medical violates the Interstate Commerce Clause of the United States Constitution and that the Defendants are permanently enjoined from denying claims submitted by Gordian Medical for the 20% coinsurance and annual deductible payment for medical supplies provided to dual-eligible beneficiaries under Medicare Part B on the basis of 10A N.C.A.C. 22O.0119.

7. Issue a judgment declaring that the Defendants’ denial of Gordian Medical’s application for enrollment as a provider in the North Carolina Medicaid program because Gordian Medical does not maintain a physical location within the State of North Carolina or within the “border area,” and lacking such a physical location, because the medical supplies provided by Gordian Medical are not “unique” in that such supplies are available “through an enrolled provider located within the state or border area” violates the Equal Protection Clause of the Fourteenth Amendment to the United States Constitution and that the Defendants are permanently enjoined from excluding Gordian Medical as a provider in the North Carolina Medicaid program because Gordian Medical does not maintain a physical location within the



State of North Carolina or within the “border area,” and lacking such a physical location, because the medical supplies provided by Gordian Medical are not “unique” in that such supplies are available “through an enrolled provider located within the state or border area.”

8. Issue a judgment declaring that the Defendants’ enforcement of the provisions of 10A N.C.A.C. 22O.0119 as to Gordian Medical violates the Equal Protection Clause of the Fourteenth Amendment to the United States Constitution and that the Defendants are permanently enjoined from enforcing the provisions of 10A N.C.A.C. 22O.0119 as to Gordian Medical.

9. Issue a judgment declaring that the Defendants’ denial of Gordian Medical’s application for enrollment as a provider in the North Carolina Medicaid program because Gordian Medical does not maintain a physical location within the State of North Carolina or within the “border area,” and lacking such a physical location, because the medical supplies provided by Gordian Medical are not “unique” in that such supplies are available “through an enrolled provider located within the state or border area” violates the Equal Protection Clause of the Fourteenth Amendment to the United States Constitution and that the Defendants are permanently enjoined from denying claims submitted by Gordian Medical for the 20% coinsurance and annual deductible payment for medical supplies provided to dual-eligible beneficiaries under Medicare Part B because Gordian Medical does not maintain a physical location within the State of North Carolina or within the “border area,” and lacking such a physical location, because the medical supplies provided by Gordian Medical are not “unique” in that such supplies are available “through an enrolled provider located within the state or border area.”

10. Issue a judgment declaring that the Defendants' enforcement of the provisions of 10A N.C.A.C. 22O.0119 as to Gordian Medical violates the Equal Protection Clause of the Fourteenth Amendment to the United States Constitution and that the Defendants are permanently enjoined from denying claims submitted by Gordian Medical for the 20% coinsurance and annual deductible payment for medical supplies provided to dual-eligible beneficiaries under Medicare Part B on the basis of 10A N.C.A.C. 22O.0119.

11. Award Gordian Medical damages equal to the total value of coinsurance claims unlawfully denied by the Department since Gordian Medical's first submission of such a claim on or about August 8, 2008, through the date of judgment; or in the alternative, the total value of coinsurance claims denied by the Department since Gordian Medical's submission to the Department on February 26, 2009, of its application to become an approved North Carolina Medicaid Provider, through the date of judgment.

12. Tax the costs, fees, and expenses of this action against the Defendants; and

13. Grant such other and further relief as the Court may deem just and proper.

Respectfully submitted this, the 4<sup>th</sup> day of February, 2010.

NELSON MULLINS RILEY & SCARBOROUGH LLP

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*Counsel for Plaintiff Gordian Medical, Inc.*

VERIFICATION

I, Gerald Del Signore, declare that I am the Chief Executive Officer of Gordian Medical, Inc., that I have read the Verified Complaint and know the contents thereof, and that the same are true and correct to the best of my own knowledge, except to those matters therein stated to be alleged upon information and belief, and as to those matters I believe them to be true.

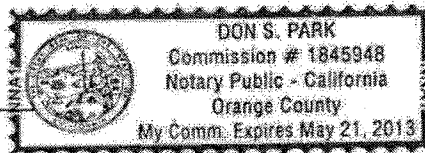
Gordian Medical, Inc.

By:



Gerald Del Signore  
Chief Executive Officer

Sworn to and subscribed before me  
this 3<sup>RD</sup> day of February, 2010.

  
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Notary Public

My Commission Expires:

MAY 21, 2013